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# MedStar Health

**VIA Facsimile and U. S. Mail**

September 4, 2007

David A. Neumann, PhD
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Comments on Proposed Amendments to COMAR 10.24.05
*Research Waiver Applications: Atlantic C-PORT Study of Non-Primary Percutaneous Coronary Intervention (non-primary PCI)*

Dear Dr. Neumann:

MedStar Health appreciates the opportunity to submit the following comments for your consideration on the above-referenced proposed regulations, published in the *Maryland Register* on August 3, 2007.

MedStar Health is a community-based non-profit healthcare organization that includes seven major hospitals in the Baltimore-Washington area. These hospitals are: Franklin Square Hospital Center, Good Samaritan Hospital, Harbor Hospital, and Union Memorial Hospital in Maryland, and Washington Hospital Center, Georgetown University Hospital and National Rehabilitation Hospital in Washington, D.C. Union Memorial Hospital and Washington Hospital Center both offer a full range of cardiac care services, including open-heart surgery and angioplasty services. Washington Hospital Center is one of the largest and most highly regarded providers of cardiac services in the region. Both Union Memorial and Washington Hospital Center are consistently recognized for superior outcomes in open-heart surgery and angioplasty services. Franklin Square Hospital Center currently holds a waiver from the Maryland Health Care Commission (MHCC) to perform primary PCI.

MedStar Health's position on the C-PORT non-primary PCI study is that study should not move forward for ethical and other reasons, nevertheless we are taking the opportunity to comment on the Proposed Regulations, but these comments should not be construed as change in our prior position.

**1. *Clarify Procedure at End of Study Period***

*MedStar Health suggests that the Commission specify in regulation the process for transitioning hospitals that receive waivers to participant in the C-PORT non-primary PCI study upon termination of the study period or termination of the waiver by action of the Commission.*

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MedStar Health believes the proposed regulations could do a much better job of anticipating and planning for the possible alternative outcomes of the study.[1] Specifically, the regulations must set forth the procedures for terminating the waivers and potentially transitioning back to the current non-primary PCI policy regarding surgical backup or revised policies and/or regulations. The Commission needs an additional rule addressing how the waiver hospitals will transition from performing non-primary PCI services pursuant to this temporary waiver and an interim period in which final policies are developed. The amorphous implication that the waivers will terminate after two years is not enough. Because the proposed regulations are vague on this point, the Commission risks misleading hospitals that may make investment decisions on equipment and personnel based on a belief or expectation that their non-primary PCI service is likely a permanent one.

The Commission should be well aware of the potential difficulty it will face at the end of the C-PORT study period. At that time, it would be appropriate to require the waiver hospitals to stop performing non-primary PCI. However, once the infrastructure is in place, such as the designated space, staff, equipment and physician referral patterns, those hospitals would naturally want to find a way to continue the service to their patients. The Commission has no precedent for requiring a hospital to discontinue a service. **In fact, the Commission has shown a reluctance to terminate an existing service under its clear authority to do so, even if that service does not meet the Commission's own established quality of care criteria.** Thus it is imperative that the Commission establish this framework *in advance*.

*Therefore, MedStar Health suggests that language be added to the proposed regulations stating that under no condition will a waiver be renewed to extend non-primary PCI services, and requiring that the waiver hospital cease operation of non-primary PCI services at a specified time following the end of the study or termination of the waiver by the Commission.* This will assure that providers know what to expect at the study's conclusion. If the data analysis eventually results in policy change, the Commission will then have a clear and level playing field on which to begin a new ballgame.

## Additional Comments on the Proposed Regulations

MedStar Health submitted comments on the draft regulations dated May 25, 2007 offering suggested changes should the study go forward that were intended to help improve appropriate access to the C-PORT study, and the quality and cost effectiveness of the waiver services. An updated list of those suggestions follows.

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[1] The Commission should clarify more of its possible next steps. The Commission has not described whether the PCI service would be approved by another waiver process, or would be subject to certificate of need (CON) approval. MedStar believes that public input, as is allowed in the CON process, is important when establishing permanent new services.

*2. Meeting the Criteria for Primary PCI Waivers.*

*Because the criteria for granting primary PCI waivers is used in part as the basis for granting waivers for non-primary PCI, the Commission should strictly enforce the primary PCI criteria.*

**MedStar Health is very concerned that the Commission has already demonstrated that it will not enforce the primary PCI criteria, with the potential implications for quality of care in the non-primary PCI programs.** In 2006, the Commission granted several Baltimore Metropolitan and Washington Metropolitan region hospitals conditional one-year waivers to perform primary angioplasty. Even though many of these hospitals had been performing primary PCI for several years (in the original C-PORT study), initially the Commission did not grant these hospitals two-year waivers because of their failure to meet one or more of the criteria established for primary waiver hospitals, such as door to balloon time and volume requirements. However, some of the waiver hospitals received approval to renew their primary waivers **even though they did not meet the criteria after a year of treating patients**. If these criteria are not important to quality of care they are meaningless and should be dropped from the regulations. Otherwise, the regulations should be enforced by the Commission, and waivers should not be renewed for any hospital which does not meet the criteria.

*3. Informed Consent*

*The Commission should require documentation that each participating facility has a sound plan to secure informed consent for study participants, ensuring that participants understand the goals of the study, the risk of participating in the study, and are advised of less risky treatment alternatives available to them.*

The issues raised recently with the focus on transparency in health care relate to disclosure of all types of information, not just costs. The proposed regulations could be improved to better address informed consent of the participants. Given the finding of the Commission's Advisory Committee on Outcome Assessment in Cardiovascular Care Interventional Cardiology Subcommittee that there are no clinical benefits to be derived for the patients who participate in the study, it is important that those who are being asked to participate in the study know this. Also, given that preferences are contemplated in the selection criteria for those programs that expand access to minority populations, many who are currently underserved, it is acutely important that the study population is balanced in terms of representation and not overly represented by minorities. Specific efforts should be made to ensure that minority populations, many whom may not have personal primary care providers, be informed of the options for care available to them other than through the study.

***4. The Commission may grant a waiver for no more than six (6) hospitals, .02C.***

*The proposed regulation should specify that the number of waivers should be allocated based on region, with each region allotted one waiver slot.*

This regulation as written does not reflect Commission policy on geographic distribution of the waivers. There is nothing in the proposed regulation that prevents the MHCC from granting six waivers in one region only, or that requires an even distribution of the six waivers. The Commission and the staff have previously expressed the view that a primary reason for allowing expansion of PCI services is to improve the ability of rural hospitals to perform PCI. It therefore follows that the majority of waiver sites for primary PCI should be granted to rural hospitals. Moreover, for the Baltimore Metropolitan Region and the Washington Metropolitan Region, where there is much better access to PCI services than either Western Maryland or the Eastern Shore Region, the regulation should require substantial additional justification to grant more than one waiver. There must be a compelling justification for exposing patients to additional risk with no corresponding clinical benefit.

***5. Eligibility to File an Application, 03.B.***

*An additional requirement to be eligible to file an application for a hospital in the Metropolitan Baltimore and Washington regions should be that the applicant is at least five (5) miles from an existing open-heart surgery center.*

Many of the hospitals in the Baltimore or Washington regions are located very near existing tertiary hospitals. These hospitals typically draw their interventional cardiologists from the same pool of interventionalists that serve the nearby tertiary hospitals, so allowing non-primary PCI at these centers will not account for any significant improvements in access to the primary PCI services at these hospitals. Additional competition for the same pool of scarce staff and physician resources will increase costs substantially. The five-mile requirement, therefore, should help assure that geographic access is improved, and may help to minimize the cost impact from programs that share the same staff.

***6. Physician Resources, .04A (2)(b).***

*The requirement for three interventional cardiologists will leave no room for illness, vacation or conflicting schedules. Accordingly, requiring 4 or 5 interventional cardiologists would be essential for 24/7 coverage and therefore more appropriate.*

Staff shortages and increased competition for scarce staff are likely to result from expanding PCI services. While increasing the number of required interventionalists will admittedly add to this pressure, the reality is that requiring only three interventionalists will lead to insufficient coverage.

***7. Additional Review Criteria, .04.A (3).***

In our previous written comments on the draft regulations, dated May 25, 2007, we suggested that, in addition to the five review criteria regarding access and data, four additional requirements be added to the proposed regulation. *The Commission should be required to consider whether granting a waiver application will: 1) have an adverse impact on existing elective PCI providers; 2) raise the cost of health care in the State; 3) cause or contribute to a shortage of the highly trained staff necessary to run catheterization labs; and 4) before granting any waivers, the Commission should also be required to consider whether the C-PORT study, based on its historical performance, is likely to produce reliable results.*

The C-PORT study has been enrolling patients for a year and a half. Data for this year and a half period (which represents almost 2/3 of the projected study period of 28 months) already indicates that the study may not produce reliable results. For instance, the actual enrollment rate per hospital is approximately 127 patients annualized versus the study's anticipated 200 patients. In addition, the study, originally predicted to last for 28 months (which would be an end date of mid-2008), is now projected to run much longer, resulting in significant additional costs. However, there is no projection as to where the necessary additional funding will come from. In his recommendation, Dr. Cowdry notes that the cost of the study is likely to be around four million dollars, and stated that the ability to meet the costs of the study is a concern. For that reason he states that funding should be closely monitored in the future. However, presumably the hospitals that have been participating in the study since early 2006 have already made their two-year contributions to the study (which were most likely based on the original study's cost projection of $34,000 per year and not the revised study's projected costs of $52,500 per year). It should therefore be a simple matter to determine as of today, how much of the projected $4 million in funding the study currently has actually received.

***8. Waiver Term, .05.A.***

The proposed regulation currently states:
***A waiver to perform non-primary PCI issued by the Commission will expire on the earlier of:***
***(1) Two years from the date on which the Waiver was first issued;***
***(2) The date patient accrual into the C-PORT study ends;***
***(3) A finding made by the Commission that the C-PORT study is not accruing patients at an acceptable rate; or***
***(4) A finding by the Commission that the C-PORT study is unlikely to produce reliable results to guide public policy.***

*MedStar believes that this section must be far more specific as to the non-renewability of PCI services after the temporary waiver, and the period of data analysis and policy development. As stated above, MedStar is concerned about the potential for the Commission to allow the services*

*to continue once they have been operational for a year or more without more definitive language to the contrary.*

In our May 25, 2007 letter we also suggested that waivers should be granted for a maximum of one year, not two years, so that the Commission may do a better job of monitoring whether the applicant is meeting the volume and other requirements of the study and the regulations. Granting only one-year waivers would be consistent with the current process for granting initial waiver applications to perform primary angioplasty. This would also provide a definitive timeframe and process for a re-evaluation of the study's overall experience and an assessment of the continuing likelihood that the study will produce reliable results.

***9. Interested Parties and Participating Entities.***

*The proposed regulations should allow for comments on applications by interested parties and participating entities.*

The Commission should be required to consider adverse impact on existing providers and the cost implications of granting a waiver to participate in the study. Accordingly, the Commission should allow interested parties to comment on applications, particularly to demonstrate the impact that granting the application will have on the interested party's operations and ability to provide quality medical services. Likewise, the Commission should take comments from participating entities such as payors, particularly with respect to increased costs, which may result from granting an application.

The Commission should consider the comments of interested parties and participating entities even though the waivers that will be granted are only to participate in the study and are, theoretically, temporary in nature. The proposed regulations provide that the Commission may extend a waiver beyond the currently proposed two-year period. Because the study's lead researcher has predicted that the study may last twice as long as was initially projected, it is possible that Maryland waivers may extend well beyond two years. This, coupled with the 1-to-3 randomization scheme of the study (for every 4 patients, 3 patients which ordinarily would have been diverted to a nearby heart center will remain at the waiver hospital) could lead to significant adverse impact on existing providers, as well as increased costs to payors, despite the temporary nature of the waiver.

***10. Cost of Initiating New Services.***

*To obtain data that will help inform future public policy development, the Commission should also require documentation of the projected and/or actual incremental costs (for equipment, transportation and staffing, including all costs related to contracts and other arrangements with physicians related to physician coverage) to the applicant to participate in the study, in the initial application.*

The Commission has previously raised many of these concerns as real concerns regarding the de-centralization of angioplasty services in the State. Selection of certain waiver sites will have a definite negative impact on costs to the health system and on existing heart centers. Pulling volume from a strong heart center to bolster volume at a nearby community hospital will only serve to decrease overall quality of care in the State by creating a pool of mediocre providers versus having a select number of centers of excellence. Evidence establishes that, due to economies of scale, the cost to perform non-primary PCI is significantly greater ($6,084 per procedure in 2002) at a low volume hospital versus the cost at high volume hospitals. Finally, there are a finite number of highly qualified interventional cardiologists and staff necessary for performing PCIs and running catheterization labs. Broadening the field of hospitals providing such services will only create bidding wars for these physicians and staff. **Because future public policy development would only benefit from this type of data, the Commission should collect it now.**

MedStar Health respectfully asserts our prior position that a non-primary PCI study should not go forward, but if it does, the foregoing suggestions will result in regulations that will better achieve high volumes, cost effectiveness, and improvement in geographic access—the stated goals that underlie this initiative.

Sincerely,

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cc: Kenneth A. Samet
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